DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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September 20, 2004

**WARNING LETTER NO. 2004-NOL-37**

**FEDERAL EXPRESS**
**OVERNIGHT DELIVERY**

Mr. Thi V. Le, Owner
Jennifer Le Seafood
287 Division Street
Biloxi, Mississippi 39530

Dear Mr. Le:

On May 19, 20, 24 & 25, 2004, a United States Food and Drug Administration (FDA) investigator inspected your firm, located at 287 Division Street, Biloxi, Mississippi. We found you have serious deviations from the Fish and Fishery Products Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your cooked, ready-to-eat crabmeat is adulterated, as the crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

Your deviations are as follows:

1. You must implement the record keeping system you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the critical control points of "cooking," "cooling," and "product storage" to control the hazards of pathogens and pathogen growth and toxin formation as listed in your HACCP plan for cooked, ready-to-eat crabmeat.

2. You must conduct a hazard analysis to determine whether there are food safety hazards reasonably likely to occur and have a HACCP plan listing, at minimum, the critical control points to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3 (b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can, as a result, be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for cooked, ready-to-eat crabmeat does not list a critical control point at the picking and packing processing steps for controlling the food safety hazard of pathogen growth and toxin formation.

   FDA recommends you monitor time and product temperatures during the picking and packing

processing steps. Based on our investigator's description of your process and the recommended critical limits for your cooling process, FDA recommends your critical limit ensures your crabmeat does not exceed 50°F during the picking and packing process.

3. You must have a HACCP plan listing, at minimum, the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cooked, ready-to-eat crabmeat lists a critical limit "[redacted]" which is not adequate for controlling the food safety hazard of pathogen growth and toxin formation. Since your crabmeat is [redacted], FDA recommends your product be cooled [redacted], not [redacted]

4. You must maintain sanitation control records to document, at a minimum, monitoring and corrections to comply with 21 CFR 123.11(c). However, from the beginning of your firm's operations in May 2003 until the date of our inspection on May 19, 2004, your firm did not maintain sanitation monitoring records for the following: the safety of water coming into contact with food or food contact surfaces, including water used to manufacture ice; condition and cleanliness of food contact surfaces; prevention of cross-contamination from insanitary objects; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration; proper labeling, storage, and use of toxic chemicals; control of employee health conditions; and, exclusion of pests required for the processing of cooked, ready-to-eat crabmeat.

5. You must monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces; prevention of cross-contamination from insanitary objects; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food and food contact surfaces from adulteration; and exclusion of pests as evidenced by the following:

Prevention of cross-contamination

a. Our investigator observed employees placing back into production cooked crabs that had fallen on the floor.

b. On May 19 and 24, 2004, customers and an employee were observed eating crabmeat at the backing table in the processing room.

c. Our investigator observed employees failing to wash and sanitize their hands after breaks.

d. Live crabs were stored in the same processing area as cooked crabs. Our investigator observed live flies contacting cooked and live crabs.

e. Baskets used to hold cooked crabs were placed directly onto floors, were stored nested, and were not sanitized between use.

Exclusion of pests

f. Flies were observed in the processing area.

Maintenance of hand-sanitizing stations

g. The level of chlorine at the hand washing station was inadequate.

Failure to properly clean and sanitize food contact surfaces

h. An unsanitized shovel was used in the processing of crabs.

We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

We recognize at the close of the inspection you made a verbal commitment to correct the observed deficiencies. However, you must respond in writing, within 15 working days from your receipt of this letter outlining the specific things you are doing to correct these deviations. You should include in your response documentation, such as HACCP and sanitation monitoring records, or other useful information to assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the Current Good Manufacturing Practice regulation, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your response to the United States Food and Drug Administration, Attention: Cynthia R. Crocker, Compliance Officer, at 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If you have questions regarding any issue in this letter, please contact Ms. Crocker at (601) 965-4581, extension 106.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483